

Message Text

UNCLASSIFIED

PAGE 01 STATE 176493

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ORIGIN HEW-08

INFO OCT-01 ARA-16 EUR-25 EA-11 ISO-00 SCI-06 RSC-01 /068 R

66652

DRAFTED BY: DHEW/FDA/LRSHELTON

APPROVED BY: SCI/PHMILY

DHEW/OIH/MACODDING

EUR/WE:GHSHEINBAUM

EA/ANP:HLANGE

ARA/PAN:RHOWARD

----- 055824

R 131540Z AUG 74

FM SECSTATE WASHDC

TO AMEMBASSY BRUSSELS

AMCONSUL SYDNEY

AMEMBASSY PANAMA

UNCLAS STATE 176493

E.O. 11652: N/A

TAGS: TBIO, BE, AS, PN

SUBJ: RECALL OF DIAGNOSTIC PRODUCTS

1. FDA ADVISES THAT HYCEL, INC., 7920 WESTPARK DRIVE, HOUSTON, TX. 77042 IS RECALLING SEVERAL LOTS OF PHOSPHORUS REAGENTS WHICH ARE NON-EFFECTIVE FOR INTENDED USE. REAGENT ARE UNDERGOING A PROGRESSIVE CHEMICAL CHANGE WHICH MANIFESTS ITSELF BY A DECREASED LIGHT ABSORBANCE DURING THE SPECTRO-METRIC TEST PROCEDURE. CHANGES IN THE OPTICAL CHARACTERISTICS OF THE REAGENT COULD RESULT IN INCORRECT DIAGNOSIS BY GIVING A FALSE HIGH PHOSPHORUS LEVEL IN PATIENT SERA OR URINE AND RESULT IN IMPROPER TREATMENT WHICH COULD BE HARMFUL TO THE PATIENT.

2. FOREIGN CONSIGNEES:

HYCEL EUROPA NV, AVE. BELLE VUR L6, 1410, WATERLOO, BELGIUM
3 BTLS. SHIPPED 5/29/74 OF CATALOG NO. 235, LOT NO. 1275AL "ACID
PHOSPHATES SET KIT - 580 ML. BTL.; FOR IN-VITRO DIAGNOSTIC USE TO
DETERMINE ACID PHOSPHATASE IN SERUM".

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PRO MED SA, PANAMA 5, PANAMA 24 BTLS. SHIPPED 5/22/74 OF CATALOG
NO. 198 AMX, LOT NO. 1348AL, 1294AL, 1280AL, 1275AL, OR 1087BL
PHOSPHOROUS REAGENT, 1890 ML. BTL. FOR IN-VITRO DIAGNOSTIC USE
TO DETERMINE INORGANIC PHOSPHORUS IN SERUM AND URINE."

MCGAW IND PTY LTD., NORTH SYDNEY, AUSTRALIA. 12 BTLS. SHIPPED
5/29/74 OF CAT. NO. 198A, LOT NO. 1348AL, 1294AL, 1280AL
1275AL, OR 1087AL "PHOSPHORUS REAGENT, 580 ML. BTL. FOR
IN-VITRO DIAGNOSTIC USE TO DETERMINE INORGANIC PHOSPHORUS IN
SERUM AND URINE".

3. POST REQUESTED TO CHECK WITH CONSIGNEES TO DETERMINE IF RECALL
INSTRUCTIONS HAVE BEEN RECEIVED AND ACTED UPON. KISSINGER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: RECALLS, PHOSPHORUS, CHEMICALS
Control Number: n/a
Copy: SINGLE
Draft Date: 13 AUG 1974
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1974STATE176493
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Document Unique ID: 00
Drafter: DHEW/FDA/LRSHELTON
Enclosure: n/a
Executive Order: N/A
Errors: N/A
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From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1974/newtext/t19740851/aaaabrff.tel
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Locator: TEXT ON-LINE, ON MICROFILM
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Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
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Previous Channel Indicators:
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Previous Handling Restrictions: n/a
Reference: n/a
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Review Authority: golinofr
Review Comment: n/a
Review Content Flags:
Review Date: 08 JUL 2002
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Review Exemptions: n/a
Review History: RELEASED <08 JUL 2002 by reddocgw>; APPROVED <09 JUL 2002 by golinofr>
Review Markings:

Declassified/Released
US Department of State
EO Systematic Review
30 JUN 2005

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: RECALL OF DIAGNOSTIC PRODUCTS
TAGS: TBIO, BE, AS, PN
To: BRUSSELS PANAMA
Type: TE
Markings: Declassified/Released US Department of State EO Systematic Review 30 JUN 2005